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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/072,247	10/23/2001	Daniel J. Cook	39726/29361	4051
1688	7590	12/15/2004	EXAMINER	
POLSTER, LIEDER, WOODRUFF & LUCCHESI 12412 POWERSCOURT DRIVE SUITE 200 ST. LOUIS, MO 63131-3615			PATEL, MITAL B	
			ART UNIT	PAPER NUMBER
			3743	

DATE MAILED: 12/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/072,247

Applicant(s)

COOK, DANIEL J.

Examiner

Mital B. Patel

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 September 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 10-16 and 19 is/are allowed.
- 6) ☒ Claim(s) 1-9, 17, 18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- 1) ☐ Certified copies of the priority documents have been received.
 - 2) ☐ Certified copies of the priority documents have been received in Application No. _____.
 - 3) ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Response to Amendment/Arguments

1. Applicant's arguments filed 9/15/04 have been fully considered but they are not persuasive.
2. In response to applicant's argument that DiPietropolo teaches a device for shaping the medullary space of a bone rather than a device for retaining an endotracheal tube, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963).
3. In response to Applicant's arguments that the connection adapter of DiPietropolo is not a soft, semi-rigid material, the Examiner directs Applicant's attention to the definition of soft, which the Applicant provided in the arguments, specifically, yielding to physical pressure. As such, the Examiner contends that the connection adapter of DiPietropolo would yield at or to some physical pressure. Furthermore, Applicant has not specified in the disclosure what the term "soft, semi-rigid" is limited to, and therefore, the Examiner maintains the rejection set forth in the previous office action.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1-4, 6, 8, 9, and 17 are rejected under 35 U.S.C. 102(b) as being anticipated by DiPietropolo (US 4,751,922).

6. **As to claim 1**, DiPietropolo teaches an endo-tracheal tube retainer (**it should be noted that because DiPietropolo teaches all the structure set forth in claim 1 below, it is inherently capable of retaining an endo-tracheal tube**) comprising a solid (**See Col. 4, lines 25-26 and lines 32-35, which disclose that the rod *may be* (emphasis) bored which the Examiner interprets to mean that DiPietropolo also teaches a solid rod; additionally, the Examiner contends that even if the rod is bored, it receives a guide-pin which would make the rod solid**) semi-rigid (**See Fig. 2 which shows the rod being flexible yet still able to maintain rigidity as depicted in Fig. 1; See also Col. 4, lines 23-24**) stylet rod **1** having proximal and distal ends, said stylet rod **1** having a base portion at the distal end of the rod integral with said distal end (**See Col. 4, lines 36-55**); and a connection adapter **3** tapered from a proximal end of said connection adapter **3** to a distal end (**See Fig. 1 attachment below**) of said connection adapter **3** for secure insertion within a range of endotracheal tubes, said adapter **3** being connected to said base portion of the distal end of said solid stylet rod **1** (**See Col. 4, lines 36-55**), wherein at least a portion of the connection

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adapter 3 has an outer diameter in the range of about 2.0 mm to about 14.0 mm (**See Col. 4, lines 28-29 which teaches a 13 mm adaptor which falls within the range recited).**

7. **As to claim 2**, DiPietropolo teaches an endo-tracheal tube retainer (**it should be noted that because DiPietropolo teaches all the structure set forth in claim 1 below, it is inherently capable of retaining an endo-tracheal tube**) wherein the endo-tracheal tube retainer is used to facilitate the removal of the laryngeal mask of the type having a flexible respiratory tube, and that is sufficiently small in diameter to pass through a flexible respiratory tube (**Please note that DiPietropolo teaches all of the structure recited in claim 1 and as such is inherently capable of performing the function set forth in claim 2).**

8. **As to claim 3**, DiPietropolo teaches an endo-tracheal tube retainer (**it should be noted that because DiPietropolo teaches all the structure set forth in claim 1 below, it is inherently capable of retaining an endo-tracheal tube**) wherein the stylet 1 is adapted for use independently of the endo-tracheal tube as an intubating stylet (**Please note that DiPietropolo teaches all of the structure recited in claim 1 and as such is inherently capable of performing the function set forth in claim 3).**

9. **As to claim 4**, DiPietropolo teaches an endo-tracheal tube retainer wherein the semi-rigid stylet 1 is of sufficient length (**Please note that Applicant has not clearly defined what this sufficient length constitutes, however, please see Col. 4, lines 27-31 which teaches a stylet length of 20 inches which is more than a sufficient**

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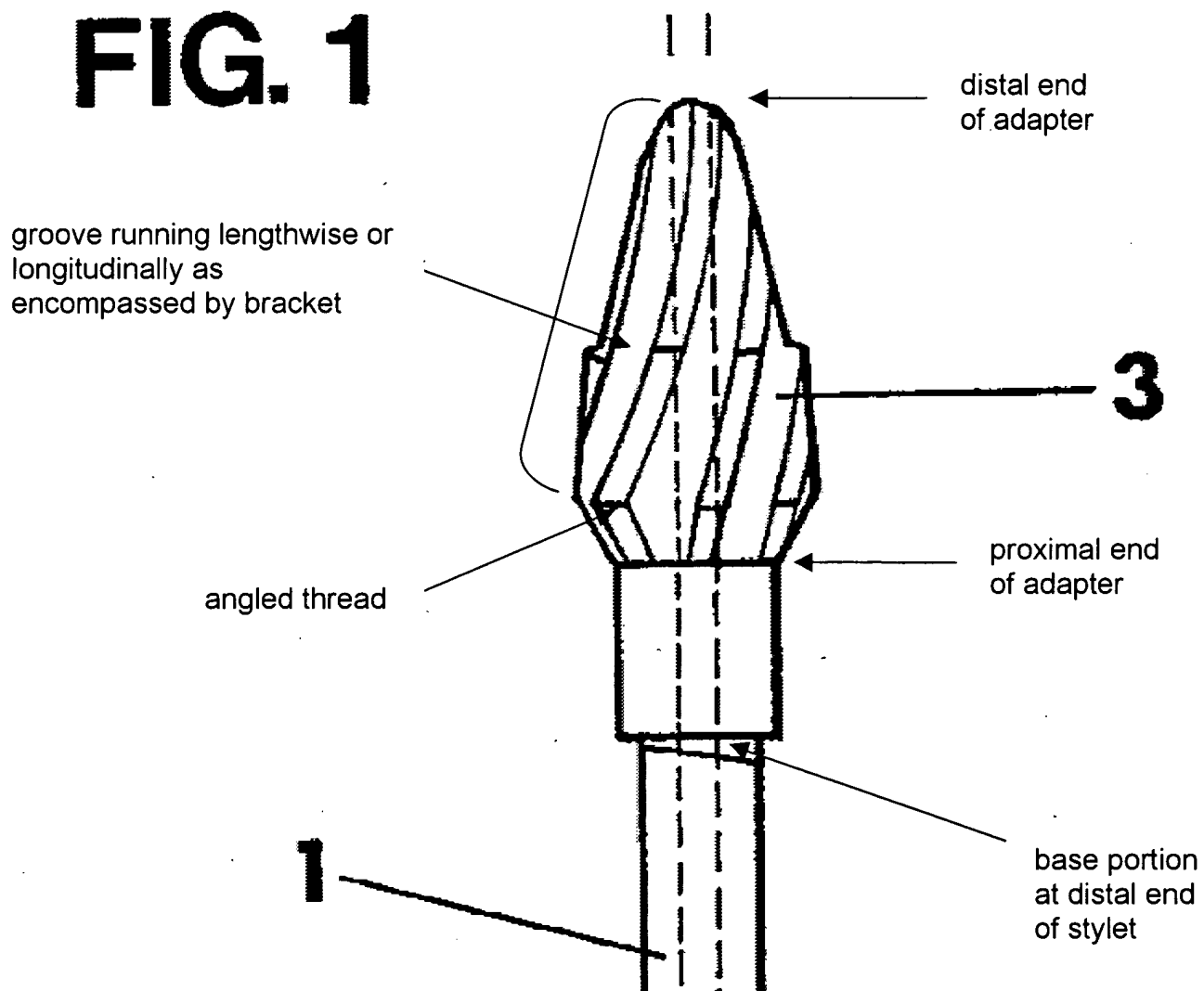
length to perform the function set forth) to extend from the laryngeal opening to a point external to a patient's oral cavity.

10. **As to claim 6**, DiPietropolo teaches an endo-tracheal tube retainer wherein an exterior surface of the connection adapter **3** comprises a plurality of longitudinal grooves **(Please see Fig. 1 attachment below; Also note that longitudinal is defined in Merriam-Webster's Collegiate Dictionary, 10th Ed. as placed or running lengthwise and the Examiner considers DiPietropolo to teach grooves running lengthwise on the adaptor from one end lengthwise to the other end; furthermore, Applicant recites longitudinal grooves on an exterior surface and does not recite longitudinal grooves running along the entire length of the exterior surface of the adaptor)** permitting passage of air and fluids past the endo-tracheal tube retainer after insertion within an endo-tracheal tube; and a plurality of threads angled **(See Fig. 1 attachment below)** to facilitate insertion of said endo-tracheal tube retainer within an endo-tracheal tube, but hindering withdrawal of said endo-tracheal tube retainer from said endo-tracheal tube **(Please note that given the structure the device is inherently capable of performing the functions set forth)**.

11. **As to claim 8**, DiPietropolo teaches an endo-tracheal tube retainer wherein the longitudinal grooves are equi-spaced around the connection adapter **3** exterior surface **(See Fig. 1 attachment below)**.

12. **As to claim 9**, DiPietropolo teaches an endo-tracheal retainer wherein there are at least four longitudinal grooves **(See Fig. 1 attachment below; please note only 3 are shown, the remaining grooves being on the other side of the adapter)**.

FIG. 1



13. As to claim 17, DiPietropolo teaches an endo-tracheal tube retainer (it should be noted that because DiPietropolo teaches all the structure set forth in claim 17

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below, it is inherently capable of retaining an endo-tracheal tube) comprising a solid (See Col. 4, lines 25-26 and lines 32-35, which disclose that the rod *may be* (emphasis) bored which the Examiner interprets to mean that DiPietropolo also teaches a solid rod; additionally, the Examiner contends that even if the rod is bored, it receives a guide-pin which would make the rod solid) semi-rigid (See Fig. 2 which shows the rod being flexible yet still able to maintain rigidity as depicted in Fig. 1; See also Col. 4, lines 23-24) stylet rod 1 having proximal and distal ends, said stylet rod having a base portion at the distal end of the rod integral with said distal end (See Col. 4, lines 36-55); and a connection adapter 3 tapered from a proximal end of said connection adapter 3 to a distal end (See Fig. 1 attachment above) of said connection adapter 3 for secure insertion within a range of endotracheal tubes, said adapter 3 being connected to said base portion of the distal end of said solid stylet rod 1 (See Col. 4, lines 36-55), wherein at least a portion of the connection adapter has an outer diameter in the range of about 2.0 mm to about 14.0 mm (See Col. 4, lines 28-29 which teaches a 13 mm adaptor which falls within the range recited), and wherein an exterior surface of the connection adapter 3 comprises a plurality of longitudinal grooves (Please see Fig. 1 attachment above; Also note that longitudinal is defined in Merriam-Webster's Collegiate Dictionary, 10th Ed. as placed or running lengthwise and the Examiner considers DiPietropolo to teach grooves running lengthwise on the adaptor from one end lengthwise to the other end; furthermore, Applicant recites longitudinal grooves on an exterior surface and does not recite longitudinal grooves running along the entire length of the exterior surface of the

adaptor) permitting passage of air and fluids past the endo-tracheal tube retainer after insertion within an endo-tracheal tube; and a plurality of threads angled (**See Fig. 1 attachment above**) to facilitate insertion of said endo-tracheal tube retainer within an endo-tracheal tube, but hindering withdrawal of said endo-tracheal tube retainer from said endo-tracheal tube (**Please note that given the structure the device is inherently capable of performing the functions set forth**).

14. **As to claim 18**, DiPietropolo teaches an endotracheal tube retainer (it should be noted that because DiPietropolo teaches all the structure set forth in claim 17 below, it is inherently capable of retaining an endo-tracheal tube) comprising: a solid (**See Col. 4, lines 25-26 and lines 32-35, which disclose that the rod *may be* (emphasis) bored** which the Examiner interprets to mean that DiPietropolo also teaches a solid rod; additionally, the Examiner contends that even if the rod is bored, it receives a guide-pin which would make the rod solid) semi-rigid (**See Fig. 2 which shows the rod being flexible yet still able to maintain rigidity as depicted in Fig. 1; See also Col. 4, lines 23-24**) stylet rod **1** having proximal and distal ends, said stylet rod having a base portion at the distal end of the rod integral with said distal end (**See Col. 4, lines 36-55**); and a connection adapter **3** tapered from a proximal end of said connection adapter to a distal end of said connection adapter for secure insertion within a range of endotracheal tubes said adapter (**See Fig. 1 attachment above**) being connected to said base portion of the distal end of said solid stylet rod wherein at least a portion of the connection adapter has an outer diameter in the range of about 2.0 mm to about 14.0 mm (**See Col. 4, lines 28-29 which teaches a 13 mm**

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adaptor which falls within the range recited), and wherein the connection adapter is composed of soft semi-rigid material, sufficiently flexible to permit said connection adapter to traverse through said endotracheal tube after positioning within the oropharynx region.

Claim Rejections - 35 USC § 103

15. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

16. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over DiPietropolo (US 4,751,922) over Stone et al (US 5,525,316).

17. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

18. **As to claim 7**, DiPietropolo teaches essentially all of the limitations except for wherein the connection adapter is composed of soft, semi-rigid material sufficiently flexible to permit the connection adapter to traverse through the endo-tracheal tube after positioning within the oropharynx region. Stone et al also teaches a reamer with a

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connection adaptor/head which is composed of a soft, semi-rigid material sufficiently flexible (**See Col. 3, lines 39-40 of Stone et al, it should be noted that with respect to the descriptors "soft, semi-rigid", Applicant's connection adaptor is threaded and therefore, Examiner interprets soft, semi-rigid to mean that it is made of a material that would allow for the adaptor to flex and as such Stone et al teaches a soft, semi-rigid material**) so that the adaptor may be able to flex and curve relative to its axis in order to follow the shape of a particular anatomy of the patient. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the adaptor of DiPietropolo to be flexible as taught by Stone et al so that the adaptor may flex and curve relative to its axis in order to follow the natural curve of a particular anatomy of the patient (**Please note that both the DiPietropolo reference and Stone et al reference are analogous art since both are of the reamer art, thereby making the 103(a) rejection proper to arrive at the recited structural limitations; and therefore, having the structure results in an inherent capability to perform the intended use/function**).

Allowable Subject Matter

19. Claims 10-16 and 19 are allowed over the prior art of record. Please note that claim 19 would be subject to a double patenting rejection. However, Applicant has filed a terminal disclaimer in response to the double patenting rejection set forth in the previous office action. As such, newly presented claim 19 is covered by the terminal disclaimer filed 9/15/04.

Conclusion

20. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

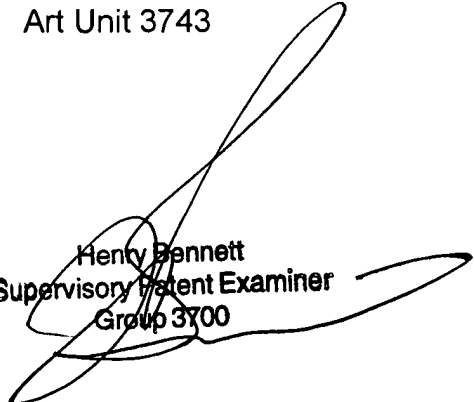
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mital B. Patel whose telephone number is 571-272-4802. The examiner can normally be reached on Monday-Friday (11:00-7:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry Bennett can be reached on 571-272-4791. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Mital B. Patel
Examiner
Art Unit 3743



Henry Bennett
Supervisory Patent Examiner
Group 3700